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510(k) Summary

for

Arthro Kinetics Endoscopic Spine System

1. SPONSOR

Arthro Kinetics Inc.
8 Faneuil Hall, 3rd Floor
Boston, MA 02109

Contact Person: James Hobbs
Telephone: 508-735-3810

Date Prepared: July 26, 2006

2. DEVICE NAME

Proprietary Name: Endoscopic Spine System
Common/Usual Name: Spinal Access System
Classification Name: Arthroscope and Accessories

3. PREDICATE DEVICES

- Endius Atari System (K053267)
- Henke-Sass Wolf Endoscope (K941967)
- Joimax Thessys Multiscope (K051827)
- Viking Systems CCD camera (K941919)

4. DEVICE DESCRIPTION

The Arthro Kinetics Endoscopic Spine System consists of an Endoscope, light source, light guide, sheaths, camera head, and camera control unit and is a reusable minimally invasive system that enables surgeons to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as nucleotomy, discectomy, and foraminotomy. The outer sheath acts to facilitate

suction / irrigation to the surgical site, serving as a cannula to provide an access portal for the endoscope to be inserted into the patient for viewing or the placing of manual surgical instruments. By inserting the endoscope into the outer sheath the surgeon will be able to view the operative site whilst being guided to the pain source by the ongoing feedback from the patient. The endoscope also has a working channel to allow surgical instruments to be inserted into the operative site.

5. INTENDED USE

The Arthro Kinetics' Endoscopic Spine System (Kinetics Interchangeable Spine System) is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as nucleotomy, discectomy, and foraminotomy.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Arthro Kinetics Endoscopic Spine System and the predicate devices all include working channels and/or irrigation channels used to visualize and irrigate the operative site. The proposed and predicate devices include a fiberoptic or rod/lens endoscope, camera and light source for visualization. Additionally, they all contain working channels and irrigation channels for various surgical procedures.

The technological characteristics of the Arthro Kinetics Endoscopic Spine System and the predicate products are substantially equivalent in that they all consist of an endoscope, camera, control unit and light source for visualization during Endoscopic spine procedures. The Arthro Kinetics Endoscopic Spine System and the predicate devices are also similar in that they all are intended specifically for spine procedures. The labeling for the Arthro Kinetics Endoscopic Spine System is essentially identical to the labeling cleared for the predicate devices.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2006

Arthro Kinetics, Inc.
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K061246

Trade/Device Name: Endoscopes Spine System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: July 26, 2006
Received: July 27, 2006

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061246

510(k) Number (if known):

Device Name: Endoscopic Spine System

Indications For Use:

The Arthro Kinetics' Endoscopic Spine System (Kinetics Interchangeable Spine System) is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as nucleotomy, discectomy, and foraminotomy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
**Division of General, Restorative
and Neurological Devices**

510(k) Number K061246